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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,377	06/19/2006	Catherine J. Pachuk	051058-034000-US	3823

90162 7590 04/19/2011

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ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
04/19/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Continuation of 11. The request for reconsideration has been considered but does NOT place the application in condition for allowance for following reasons:

(**Prior rejection-maintained**) The rejection of Claims 63 and 78 under 35 USC 102(b) as being anticipated by Ill (US 5,843,770), **is maintained** for the reason of record and the reason set forth below:

Applicant argues that SEQ ID NO: 1 described by Ill et al. is a single-stranded 587 nucleotide fragment because the Sequence Listing describes that SEQ ID NO:1 is "single" stranded, and "linear", which is not "double stranded" as required by the claims.

Applicant's argument is not persuasive. The Sequence Listing requires only the primary sequences of the cited sequences, which are in linear formats. The primary sequence of SEQ ID NO:1 of the prior art, shown in the Sequence Listing, is not the conformation of SEQ ID NO:1. It is noted that the Sequence Listing of the instant application also shows that primary sequences of SEQ ID NOs: 3 and 10 are in "single" stranded and "linear" formats. Thus, Applicant's argument based on the primary sequence of SEQ ID NO:1 described in the Sequence Listing is not persuasive.

As indicated in the previous Office action (see Para 10), the RNA of SEQ ID NO: 1 of the prior art comprises "at least 19 contiguous base pair nucleotide sequence of the claimed dsRNA SEQ ID NO: 10". One of ordinary skill in the art knows that RNA inherently forms "a double-stranded conformation".

According to MPEP 2112.0, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product".

Applicant has not presented any factual evidence that the nucleic acid sequence of SEQ ID NO:1 of the prior art is not capable of forming a double-stranded conformation. For the reasons set forth above, the rejection is maintained.

(**Prior rejection-maintained**) The rejection of Claims 63 and 78 under 35 USC 102(b) as being anticipated by Sallberg (US20020155124, published on October 24, 2002: Now US Pat. 6,680,059), is **maintained** for the reason of record.

In response to Applicant's argument:

Applicant presents the same argument as Sallberg et al. does not teach or suggest that such DNA/RNA hybrids are administered or formed, particularly in vivo. One of skill in

the art One of skill in the art would understand that double-stranded DNA does not typically generate a DNA/RNA hybrid in vivo. Similarly, while Applicants agree that under the proper conditions, double-stranded DNA can be transcribed in vivo to produce a single-stranded mRNA,

This argument is not persuasive. Sallberg teaches methods of enhancing the immune response of an animal, including humans, using HBV nucleic acid-based antigen, wherein said nucleic acid-based antigens include a nucleotide sequence of HBV SEQ ID No: 14, see e.g. [0017] and [0041]. Sallberg also teaches that a nucleic acid-based antigen can comprise at least 9-25, 25-50, 50-100, 100-200, 200-500, 500-1000, 1000-2000, or 2000-4000 consecutive nucleotides of any one of SEQ ID NO: 14 or **an RNA** that corresponds to these sequences. Given that an RNA of SEQ ID NO:14 has same sequence as the instant SEQ ID NO:3, one of ordinary skill in the art would understand that the RNA of prior art would inherently form a double-stranded conformation as the RNA of the instant claims.

16. (**Prior rejection-maintained**) The rejection of Claims 63-67, 78 and 79 under 35 USC 103(a) as being unpatentable over Ill (US 5,843,770), Sallberg (US2002/0155124), and McCaffrey (Nature Biotechnology, 21(6):639-644; published online May 12, 2003), **is maintained** for the reason of record.

In response to Applicant's arguments:

Applicant presents the same arguments as above that the Ill et al. and Sallberg et al. references do not teach double stranded RNA corresponding to any sequence, let alone double stranded RNA comprising at least 19 contiguous base pair nucleotide sequence in a double-stranded conformation from within a sequence selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO: 10, wherein U is substituted for T. Moreover, McCaffrey does not teach SEQ ID NOs: 3 and 10. The combined teaching fails to teach all elements of the claims.

Applicant's arguments against the Ill et al. and Sallberg et al. references have been found not persuasive above. Applicant's argument against McCaffrey alone is not persuasive, either, because the cited Ill and Sallberg references teach dsRNA effector molecules comprising at least 19 contiguous base pair nucleotide sequence in a double-stranded conformation from with SEQ ID NO: 3 or SEQ ID NO: 10. Thus, the combined teaching has taught all elements of the claims. Also see Para 20 the Final Office action. The rejection is maintained.

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on Tu-F, 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/
Primary Examiner, Art Unit 1648